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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/717,789	11/21/2000	John A. Chiorini	14014.0323U3	8537

7590 03/26/2002

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EXAMINER	
GUZO, DAVID	

ART UNIT	PAPER NUMBER
1636	7

DATE MAILED: 03/26/2002

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No. 09/717,789	Applicant(s) CHIORINI ET AL.	
	Examiner David Guzo	Art Unit 1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____ .

2a)☐ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-45 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-45 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

11)☐ The proposed drawing correction filed on _____ is: a)☐ approved b)☐ disapproved by the Examiner.

If approved, corrected drawings are required in reply to this Office action.

12)☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

13)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____ .

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).

a) ☐ The translation of the foreign language provisional application has been received.

15)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____ .
4) ☐ Interview Summary (PTO-413) Paper No(s). _____
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: .

Election/Restriction

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

I. Claims 1-12, drawn to nucleotide sequences encoding an AAV5 vector, a AAV5 particle and recombinant AAV5 virions, classified in class 435, subclass 320.1.

II. Claims 13 and 14, drawn to a nucleic acid encoding a AAV5 rep protein, specifically SEQ ID NO:2, classified in class 536, subclass 23.72.

III. Claims 13 and 15, drawn to a nucleic acid encoding a AAV5 rep protein of SEQ ID NO:3, classified in class 536, subclass 23.72.

IV. Claims 13 and 16, drawn to a nucleic acid encoding a AAV5 rep protein of SEQ ID NO:12, classified in 536, subclass 23.72.

V. Claims 13 and 17, drawn to a nucleic acid encoding a AAV5 rep protein of SEQ ID NO:14, classified in class 536, subclass 23.72.

VI. Claims 18, 19, drawn to an isolated AAV5 rep protein of SEQ ID NO:2, classified in class 530, subclass 350.

VII. Claim 18, 20, drawn to an isolated AAV5 rep protein of SEQ ID NO:3, classified in class 530, subclass 23.72.

VIII. Claim 21, drawn to an antibody that binds to AAV5 rep, classified in class 530, subclass 387.1.

IX. Claims 22-23, drawn to an isolated AAV5 capsid protein of SEQ ID NO:4, classified in class 530, subclass 350.

X. Claims 22 and 25, drawn to an isolated AAV5 capsid protein of SEQ ID NO:5, classified in class 530, subclass 350.

XI. Claims 22, 27 and 34, drawn to an isolated AAV5 capsid protein of SEQ ID NO:6 and a particle comprising said sequence, classified in class 435, subclass 235.1.

XII. Claim 24, drawn to an isolated antibody that binds an AAV5 capsid protein of SEQ ID NO:4, classified in class 530, subclass 387.1.

XIII. Claim 26, drawn to an isolated antibody that binds AAV5 capsid protein of SEQ ID NO:5, classified in class 530, subclass 387.1.

XIV. Claim 28, drawn to an isolated antibody that binds AAV5 capsid protein SEQ ID NO:6, classified in class 530, subclass 387.1.

XV. Claims 29, 30, drawn to a nucleic acid encoding an isolated AAV5 capsid protein of SEQ ID NO:7, classified in class 536, subclass 23.72.

XVI. Claims 29, 31, drawn to a nucleic acid encoding an isolated AAV5 capsid protein of SEQ ID NO:8, classified in class 536, subclass 23.72.

XVII. Claims 29, 32, drawn to a nucleic acid encoding an isolated AAV5 capsid protein of SEQ ID NO:9, classified in class 536, subclass 23.72.

XIII. Claims 29, 33, drawn to a nucleic acid encoding an isolated AAV5 capsid protein that selectively hybridizes with a nucleic acid encoding a AAV5 capsid protein.

XIX. Claim 35, drawn to an isolated nucleic acid encoding a AAV5 p5 promoter, classified in class 536, subclass 24.1.

XX. Claim 36, drawn to a method for screening a cell for infectivity by AAV5, classified in class 435, subclass 5.

XXI. Claim 37, drawn to a method for determining the suitability of an AAV5 vector for administration to a subject, classified in class 435, subclass 7.1.

XXII. Claim 38, drawn to a method for determining the presence of anti-AAV5 specific antibodies in a subject, classified in class 435, subclass 5.

XXIII. Claims 39-43, drawn to a method for delivering a nucleic acid to a cell, classified in class 435, subclass 456.

XXIV. Claim 44, drawn to SEQ ID NO:21, classified in class 536, subclass 23.1.

XXV. Claim 45, drawn to SEQ ID NO:23, classified in class 536, subclass 23.1.

2. The inventions are distinct, each from the other because of the following reasons:

3. Inventions I and II are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions recite a AAV5 vector, nucleotide sequence encoding said vector and recombinant virion vs. a isolated sequence encoding a AAV5 rep protein. Each invention is distinct structurally, in sequence and in function, with each invention capable of supporting a separate patent. A search of one invention would not be co-extensive with a search of the other and hence would be burdensome.

4. Inventions II, III, IV and V are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve separate unique nucleotide sequences wherein one sequence would not render the other obvious. A search of one would not be co-extensive with a search of the other and hence would be burdensome. Each nucleotide sequence would be capable of supporting separate patents.

Claim 13 link(s) inventions II, III, IV and V. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), Claim 13. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

5. Inventions VI and VII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve unique, distinct AAV5 protein sequences. A search of each would not be co-extensive and hence would be burdensome. Each invention is capable of supporting a separate patent.

Claim 18 link(s) inventions VI and VII. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 18. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

6. Inventions VIII and IX are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation,

different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve biochemically, functionally and structurally distinct and unrelated molecules, (an antibody vs. an AAV5 capsid protein). Each is capable of supporting a separate patent.

7. Inventions X and XI are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions read on distinct AAV5 capsid protein sequences. A search of each would not be co-extensive with a search of the others because each possesses a distinct amino acid sequence. Each is capable of supporting a separate patent.

Claim 22 link(s) inventions X and XI. The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 22. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction

requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

8. Inventions XII, XIII and XIV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve antibodies to distinct AAV5 capsid proteins which possess distinct amino acid sequences. Each antibody is therefore unrelated as it binds to a distinct target. A search of one would not encompass a search of the other and would be burdensome.

9. Inventions XV, XVI, XVII and XVIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions read on distinct nucleic acid sequences encoding AAV5 capsid proteins. A search of each would not be co-extensive with a search of the others and hence would be burdensome. Each invention is capable of supporting a separate patent.

Claim 29 link(s) inventions XV, XVI, XVII and XVIII . The restriction requirement among the linked inventions is subject to the nonallowance of the linking claim(s), claim 29. Upon the allowance of the linking claim(s), the restriction requirement as to the linked inventions shall be withdrawn and any claim(s) depending from or otherwise including all the limitations of

the allowable linking claim(s) will be entitled to examination in the instant application. Applicant(s) are advised that if any such claim(s) depending from or including all the limitations of the allowable linking claim(s) is/are presented in a continuation or divisional application, the claims of the continuation or divisional application may be subject to provisional statutory and/or nonstatutory double patenting rejections over the claims of the instant application. Where a restriction requirement is withdrawn, the provisions of 35 U.S.C. 121 are no longer applicable. See *In re Ziegler*, 44 F.2d 1211, 1215, 170 USPQ 129, 131-32 (CCPA 1971). See also MPEP § 804.01.

10. Inventions XIX, XXIV and XXV are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions read on unrelated nucleotide sequences wherein a search of one would not be co-extensive with a search of the others and hence would be burdensome. Each invention is capable of supporting a separate patent.

11. Inventions XX, XXI, XXII and XXIII are unrelated. Inventions are unrelated if it can be shown that they are not disclosed as capable of use together and they have different modes of operation, different functions, or different effects (MPEP § 806.04, MPEP § 808.01). In the instant case the different inventions involve distinct methods each of which is directed to a

distinct, unrelated, outcome. A search of each would not be co-extensive with a search of the others and would be burdensome.

12. Because these inventions are distinct for the reasons given above and have acquired a separate status in the art because of their recognized divergent subject matter, restriction for examination purposes as indicated is proper.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

13. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(I).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to David Guzo whose telephone number is (703) 308-1906. The examiner can normally be reached on Monday-Thursday from 8:00 AM to 5:30 PM. The examiner can also be reached on alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Irem Yucel, can be reached on (703) 305-1998. The fax phone number for the organization where this application or proceeding is assigned is (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application or proceeding or relating to attachments to this Office Action should be directed to Patent Analyst Zeta Adams whose telephone number is (703) 305-3291.

DAVID GUZO
PRIMARY EXAMINER

David Guzo

March 25, 2002